



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,983	03/19/2007	Nareak Douk	PA1759	3746

28390 7590 05/18/2009
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

WOLF, MEGAN YARNALL

ART UNIT	PAPER NUMBER
----------	--------------

3738

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/560,983	Applicant(s) DOUK ET AL.	
	Examiner Megan Wolf	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/5/09 have been fully considered. Arguments regarding claims 1-3 are not persuasive. Applicant argues that the rejection of claims 1-3 as being anticipated by Houser '361 is improper because the device of Houser works by forcing a single chordae tendinae through the loops of the device and into a zigzag pattern to shorten the chordae tendinae. The examiner disagrees with Applicant's argument that using the girdle of Houser to surround a plurality of chordae tendinae (CT) would result in none of the plurality of chordae assuming the desired zigzag pattern. Surrounding a plurality of CT with the girdle of Houser will cause all of the CT to collectively assume a zigzag pattern and become effectively shortened and closer together as is claimed. Applicant's arguments are directed to the intended use of the device and the structure of Houser is capable of being used in the claimed manner.
2. Arguments regarding the rejection of claims 1-3 as being anticipated by St. Goar are not persuasive. Applicant argues that the girdle of St. Goar assumes a stacked helical coil shape rather than an annular treatment configuration. However, St. Goar specifically says in col.27 line 56 that there is no space between adjacent windings of the coil. Clearly this tightly packed coil with no space between its windings as well as the treatment configuration shown in figure 40 may be described as "annular" which simply means ring shaped. Applicant's own claim 3 states that the annular treatment configuration may be an open or closed coil.

Art Unit: 3738

3. Applicant's arguments with respect to claims 4 and 9-16 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Houser et al. 2002/0035361. Houser discloses a girdle capable of surrounding a plurality of chordae tendinae (CT) comprising filamentous body 306 comprising nitinol (par.111) to allow transition between a linear delivery configuration (21A) and an annular treatment configuration, including a coil (figs.21B, 22B), wherein the annular treatment configuration is capable of contacting a plurality of CT and drawing the plurality of CT closer together to form a bundle of effectively shortened CT.

6. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by St. Goar et al. 6,629,534. St. Goar discloses girdle 103 comprising a filamentous body of shape memory material such as nitinol to allow transition between a linear delivery configuration and an annular treatment configuration, wherein in the annular treatment configuration filamentous body 103 contacts a plurality of CT, drawing the plurality of CT

Art Unit: 3738

closer together to form a bundle of effectively shortened CT (col.27, ll.47-67; figs.39, 40).

Claim Rejections - 35 USC § 103

7. Claims 4, 9, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. 6,629,534 in view of Houser et al. 2002/0173808 (Houser '808). St. Goar discloses the invention substantially as claimed and as discussed above and further discloses a method for treating a heart valve comprising percutaneously delivering girdle 130 in lumen 124 of catheter 120 adjacent the heart valve by positioning the catheter proximate a plurality of CT of the heart valve, releasing the girdle, encircling the plurality of CT of the heart valve with the girdle, and locking the girdle into a treatment configuration (shape memory material will remain fixed or locked in the treatment configuration after it's implanted), wherein the catheter is advanced transluminally to a left ventricle through an aortic valve (fig.40; col.27, l.47-col.28, l.8). St. Goar also discloses that the girdle comprises an elongate body having first and second ends but does not disclose a locking mechanism that comprises hooks on the ends of the elongate body or a lumen lock portion and tooth on the ends of the elongate body.

Houser '808 teaches several embodiments of locking mechanisms for retaining rings, in the same field of endeavor, wherein the locking mechanism may comprise engaging hooks 128 at the ends of the elongate body (fig.11h; par.110), or a lock portion having a lumen for receiving the second end and teeth at the second end for

Art Unit: 3738

engagement with the lock portion (fig.11e; par.107), both locking mechanisms intended for the purpose of securing the ring in the closed position (pars.107,110).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the ends of the annular girdle disclosed by St. Goar to include any of the locking mechanisms taught by Houser '808 in order to more firmly secure the girdle in the annular treatment configuration.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over St. Goar et al. 6,629,534 in view of Houser et al. 2002/0173808 (Houser '808) as applied to claim 4 above, and further in view of Phillips 2003/0033006. St. Goar in view of Houser '808 discloses the invention substantially as claimed and as discussed above. However, St. Goar in view of Houser '808 does not disclose an elongate tether releasably attached to the girdle.

Phillips teaches a securing ring, in the same field of endeavor, comprising a releasable tether 70 attached to the catheter-delivered ring for the purpose of adjusting the position of the device (pars.35, 36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the girdle of St. Goar in view of Houser '808 to include a tether releasably attached thereto as taught by Phillips in order to correct and adjust the position of the device during implantation.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 3738

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738